General

Guideline Title

A consensus document on bowel preparation before colonoscopy.

Bibliographic Source(s)

Wexner SD, Beck DE, Baron TH, Fanelli RD, Hyman N, Shen B, Wasco KE, American Society of Colon and Rectal Surgeons, American Society for Gastrointestinal Endoscopy, Society of American Gastrointestinal and Endoscopic Surgeons. A consensus document on bowel preparation before colonoscopy: prepared by a task force from American Society of Colon and Rectal Surgeons, American Society for Gastrointestinal Endoscopy, and Society of American Gastrointestinal and Endoscopic Surgeons. Gastrointest Endosc. 2006 Jun;63(7):894-909. [116 references] PubMed

Guideline Status

This is the current release of the guideline.

The guideline was reaffirmed for currency by the developer in 2011.

Recommendations

Major Recommendations

The levels of evidence (I–V) and strength of recommendations (A–D) are defined at the end of the "Major Recommendations" field.

Regimens For Colonic Cleansing Before Colonoscopy

Diet

Dietary modifications alone, such as a clear liquid diet, are inadequate for colonoscopy. However they have proven to be a beneficial adjunct to other mechanical cleansing methods (Grade IIB).

Enemas

Use enemas in patients who present to endoscopy with a poor distal colon preparation and in patients with a defunctionalized distal colon.

High-Volume Gut Lavage

Neither high-volume nor unbalanced solutions, such as mannitol, should be used for colonic preparation (Grade IA). In addition, caution should be taken when using nasogastric tubes for the administration of any bowel preparation infusion (Grade VD).

Rectal Pulsed Irrigation

Rectal pulsed irrigation administered immediately before the procedure combined with magnesium citrate given the evening before the procedure is a reasonable alternative to full-volume (4-liters) polyethylene glycol (PEG) in those individuals who cannot tolerate per oral administration of PEG (Grade IIB).

PEG (Electrolyte Lavage Solution)

PEG is a faster, more effective, and better-tolerated method for cleansing the colon than a restricted diet combined with cathartics, high-volume gut lavage, or mannitol (Grade IA). PEG is safer than osmotic laxatives/sodium phosphate (NaP) for patients with electrolyte or fluid imbalances, such as renal or liver insufficiency, congestive heart failure, or liver failure and is, therefore, preferable in these patient groups (Grade IA). Divided-dose PEG regimens (2–3 liters given the night before the colonoscopy and 1–2 liters on the morning of procedure) are acceptable alternative regimens that enhance patient tolerance (Grade IIB). Cleansing preparations for colonoscopies performed in the afternoon should instruct that at least part of the PEG solution be given the morning before the procedure (Grade IIB). Enemas, bisacodyl, and metoclopramide as adjuncts to the full volume of PEG have not been demonstrated to improve colonic cleansing or patient tolerance and are, therefore, unnecessary (Grade IIB).

Sulfate-Free PEG (SF-PEG)

SF-PEG is comparable to PEG in terms of safety, effectiveness, and tolerance. SF-PEG is better tasting, but still requires the consumption of 4 liters in its standard regimen. SF-PEG is an acceptable alternative lavage solution when a PEG-based lavage solution is required (Grade IIB).

Low-Volume PEG/PEG-3350 and Bisacodyl Delayed-Release Tablets

Two-liter PEG regimens combined with bisacodyl (i.e., HalfLytely®) or magnesium citrate are equally effective compared with standard 4-liter PEG regimens but appear to be better tolerated and therefore a more acceptable alternative to the 4 liter PEG regimens (Grade IA). However, the safety of the reduced dose PEG in patients who may not tolerate fluids is still unknown. Additional studies comparing 2-liter regimens with NaP would be beneficial.

Low-Volume PEG-3350 and Bisacodyl Delayed-Release Tablets

Two-liter PEG 3350 regimens combined with bisacodyl (i.e., Miralax®) are equally effective compared with standard 4-liter PEG (Grade IA).

Aqueous NaP

Aqueous NaP colonic preparation is an equal alternative to PEG solutions except for pediatric and elderly patients, patients with bowel obstruction, and other structural intestinal disorders, gut dysmotility, renal failure, congestive heart failure, or liver failure (Grade IA). Dosing of aqueous NaP should be 45 mL in divided doses, 10 to 12 hours apart with one of the doses taken on the morning of the procedure (Grade IIB). Aqueous NaP is the preferable form of NaP at this time (Grade IIB). Apart from anecdotal reports, the addition of adjuncts to the standard NaP regimen has not demonstrated any dramatic effect on colonic cleansing preparation. Carbohydrate-electrolyte solutions such as E-Lyte® may improve safety and tolerability.

Tablet NaP

The improved taste and palatability of tablet NaP compared with aqueous NaP has not translated into improved overall patient tolerance (Grade IA). The reduced amount of microcrystalline cellulose allows for better visualization of the colonic mucosa with less need for colonic irrigation (Grade IVB). Efficacy is maintained despite decreasing the number of tablets required to complete the preparation (Grade IIB), significantly improving patient tolerance.

Adjuncts to Colonic Cleansing Before Colonoscopy

See the original guideline document for information about adjuncts to colonic cleansing before colonoscopy, including

- Flavoring
- Nasogastric/orogastric tube administration of colonic preparations
- Carbohydrate-electrolyte solutions
- Enemas
- Metoclopramide
- Simethicone
- Bisacodyl
- Saline Laxatives

Senna

Special Considerations

Inadequate Bowel Preparation

Inadequate bowel preparation for colonoscopy can result in missed lesions, cancelled procedures, increased procedural time, and a potential increase in complication rates. One study examined the possible causes for poor preparations. Surprisingly, less than 20 percent of patients with an inadequate colonic preparation reported a failure to adequately follow preparation instructions. Independent predictors of an inadequate colon preparation included a later colonoscopy starting time, failure to follow preparation instructions, inpatient status, procedural indication of constipation, use of tricyclic antidepressants, male gender, and a history of cirrhosis, stroke, or dementia. Anecdotally, a poor preparation after a PEG preparation is usually liquid and more easily managed than a preparation after NaP, which tends to be thick and tenaciously adhered to the mucosa. There is no published information on the management of the patient who has received a colonoscopy preparation that has been deemed inadequate. Regardless of the preparation selected, the patient and physician must be aware of potential financial obligations of a repeat colonoscopy and preparation. Specifically, the patient may be required to pay an additional co-pay for each examination and the financial intermediary may deem one or both examinations unnecessary. In these instances, the patient may be responsible for payment in full for both examinations. The following are recommendations (Grade VD) on management of this clinical predicament. Identify whether or not the patient has consumed the preparation as prescribed. If not, it would be reasonable to repeat the same preparation, although not within 24 hours using NaP because of the risk of toxicity. If the patient has properly consumed the preparation, reasonable options include repeating the preparation with a longer interval of dietary restriction to clear liquids, switching to an alternate but equally effective preparation (if the patient received PEG, change to NaP or vice versa), adding another cathartic, such as magnesium citrate, bisacodyl, or senna, to the previous regimen, or double administration of the preparation during a two-day period (with the exception of NaP). Combining preparations, for example PEG solution and NaP solution, also has been described with some success.

Selection of Bowel Preparation Based on Comorbidities

Elderly Patients

Elderly patients tend to have poorer preparations, although one study found no difference in the adequacy of the colonic preparation between PEG and NaP solutions. They are at an increased risk for phosphate intoxication because of decreased kidney function, concomitant medication use, and systemic and gastrointestinal diseases. Administration of NaP causes a significant rise in serum phosphate, even in patients with normal creatinine clearance. Hypokalemia is more prevalent in frail patients. However, NaP preparations may be safe in selected healthy elderly patients.

Possible Underlying Inflammatory Bowel Disease

NaP preparations may cause mucosal abnormalities that mimic Crohn's disease. However, the frequency of this problem is rare and may not mitigate against using NaP. This caveat is most important in the initial colonoscopic evaluation of patients with symptoms suspect for colitis.

Diabetes Mellitus

One study showed that patients with diabetes have significantly poorer preparations with PEG solutions than patients without diabetes, although there is no evidence that NaP preparations are superior in this group.

Pregnancy

The need for colonoscopy is uncommon during pregnancy, therefore, the safety and efficacy of colonoscopy in these individuals is not well studied. However, invasive procedures are justified when it is clear that by not doing so could expose the fetus and/or mother to harm. The safety of PEG electrolyte isotonic cathartic solutions has not been studied in pregnancy. PEG solutions are Food and Drug Administration (FDA) Category C for use in pregnancy, as defined in the FDA Current Category for Drug Use in Pregnancy, wherein no adequate and well-controlled studies have been undertaken in pregnant females and a limited number of animal studies have shown an adverse effect. The common use of PEG solutions, such as Miralax®, to manage constipation associated with pregnancy supports its safety as a bowel preparation. NaP preparations, which are also FDA Category C, may cause fluid and electrolyte abnormalities and should be used with caution.

Recommendations. If the potential benefit of colonoscopy outweighs the small but potential risks, patients may be cleansed with PEG solutions or, in select patients, a NaP preparation may be used (Grade VD).

Pediatric Population

Although there are no "national standards" per se for pediatric bowel preparations for colonoscopy, review of the literature documents the three most commonly used preparations. The least commonly used preparation is the administration of two pediatric Fleet® enemas and X-Prep® (for

age). A more widely used preparation includes Miralax® at 1.25 mg/kg per day for four days, the last day of which the child is maintained on clear liquids. This regimen is mild, well tolerated, and relatively simple to administer. The simplest preparation, both for the parents and the child, is the administration of a sugar-free, clear-liquid diet the day before and then nil by mouth for eight hours before the colonoscopy. This regimen is combined with Fleet® Phospho-soda® at a dosage of 1.5 tablespoons for children weighing less than 15 kg and 3 tablespoons for children weighing 15 kg or more, the afternoon and then again the evening before the colonoscopy. Each of these preparations is safe and will adequately prepare the child's colon for colonoscopy (Grade IA).

Definitions:

Levels of Evidence

Meta-analysis of multiple well-designed, controlled studies, randomized trials with low-false positive and low-false negative errors (high power)
At least one well-designed experimental study; randomized trials with high false-positive or high false-negative errors or both (low power)
Well-designed, quasi experimental studies, such as nonrandomized, controlled, single-group, preoperative-postoperative comparison, cohort, time, or matched case-control series
Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies
Case reports and clinical examples

Recommendation Grades

Evidence of Type I or consistent findings from multiple studies of Type II, III, or IV
Evidence of Type II, III, or IV and generally consistent findings
Evidence of Type II, III, or IV but inconsistent findings
Little or no systematic empirical evidence

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Diseases or conditions requiring a colonoscopy for colon evaluation

Guideline Category

Diagnosis

Evaluation

Management

Clinical Specialty

Gastroenterology

Intended Users

Physicians

Guideline Objective(s)

To review the evidence and provide guidelines on bowel preparation before colonoscopy

Target Population

Patients with conditions requiring colonoscopy

Interventions and Practices Considered

- Diet modification (as adjunct to other mechanical methods)
- Enemas
- High-volume gut lavage (considered, but not recommended)
- Rectal pulsed irrigation
- Polyethylene glycol (PEG) (electrolyte lavage solution)
- Sulfate-free PEG (SF-PEG)
- Low-volume PEG/PEG-3350 and bisacodyl delayed-release tablets
- Low-volume PEG-3350 and bisacodyl delayed-release tablets
- Aqueous sodium phosphate (NaP)
- Tablet NaP
- Adjuncts to colonic cleansing before colonoscopy
- Management of inadequate bowel preparation
- Selection of bowel preparation based on comorbidities, including age, possible underlying inflammatory bowel disease, diabetes mellitus, and pregnancy

Major Outcomes Considered

- Efficacy of colonic cleansing
- Patient tolerance
- Cost
- Side effects of cleansing methods

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

2006 Guideline

Not stated

2011 Currency Review Process

A review of citations from the previous guideline was augmented with searches of electronic databases including MEDLINE, PubMed, CINAHL, Embase, and Cochrane, along with review of proceedings from national meetings since 2005. The date range for all searches was from the time of the last update (2005) through 2010 inclusive. The topic searched was colonic preparation for endoscopy.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

Meta-analysis of multiple well-designed, controlled studies, randomized trials with low-false positive and low-false negative errors (high power)
At least one well-designed experimental study; randomized trials with high false-positive or high false-negative errors or both (low power)
Well-designed, quasi experimental studies, such as nonrandomized, controlled, single-group, preoperative-postoperative comparison, cohort, time, or matched case-control series
Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies
Case reports and clinical examples

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

2006 Guideline

Not stated

2011 Currency Review Process

The American Society for Gastrointestinal Endoscopy Standards of Practice Committee reviewed this guideline in August 2011. An update is anticipated in 2012.

Rating Scheme for the Strength of the Recommendations

Grade of Recommendation

Evidence of Type I or consistent findings from multiple studies of Type II, III, or IV
Evidence of Type II, III, or IV and generally consistent findings
Evidence of Type II, III, or IV but inconsistent findings

Little or no systematic empirical evidence

Cost Analysis

Table 3 in the original guideline document shows the cost of bowel preparation agents listed as average wholesale price (AWP), which is provided by the "Red Book" July 2005. As can be seen, the least expensive solution is oral sodium phosphate (NaP) and the most expensive is the tablet form of NaP. The various polyethylene glycol (PEG) preparations are intermediate in cost. None of the bowel preparation agents has an associated current procedural terminology (CPT) code that would allow for separate payment reimbursed by the patients' insurance company or Medicare in an outpatient setting. In an inpatient setting, the reimbursement for these agents would be included in the diagnosis related group (DRG) payment. Of note, patients' compliance and adequacy of bowel preparation agents can affect the direct cost for colonoscopic examination. A cost analysis has shown that inadequate bowel preparation could prolong the procedure time and increase the chance for an aborted examination and repeat colonoscopy earlier than suggested or required by current practice standards. In one study, inadequate bowel preparation led to a 12 percent increase in costs at a university hospital setting and a 22 percent increase at a public hospital setting. A meta-analysis performed on eight colonoscopist-blinded trials showed that the direct costs of colonoscopic examination (excluding the cost of bowel preparation agents) were $465 for NaP and $503 for PEG, assuming that the rates of re-examination secondary to incomplete bowel preparation for NaP and PEG were 3 and 8 percent, respectively. The results suggest that NaP is less costly than PEG with a more easily completed preparation.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

This document was reviewed and approved by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Board of Governors, the American Society of Colon and Rectal Surgeons (ASCRS) Standards Committee and Executive Council, and the American Society for Gastrointestinal Endoscopy (ASGE) Governing Board.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendation (see "Major Recommendations").

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate and complete bowel preparation before colonoscopy with minimal patient discomfort

Potential Harms

The safety of the various bowel preparation protocols currently available for use before colonoscopy is related to the safety profile of the base agent, polyethylene glycol (PEG) or sodium phosphate (NaP). Generally, all of the preparations detailed in this document have been demonstrated safe for use in otherwise healthy individuals without significant comorbid conditions. Caution should be taken in selecting a bowel preparation for patients with significant hepatic, renal, or cardiac dysfunction, and for those at the extremes of age.
The administration of isotonic PEG solution does not result in significant physiologic changes as measured by patient weight, vital signs, serum electrolytes, blood chemistries, and complete blood counts. Isotonic PEG has been safely used in patients with serum electrolyte imbalances, advanced hepatic dysfunction, acute and chronic renal failure, and congestive heart failure. PEG does not alter the histologic

features of colonic mucosa and may be used in patients suspected of having inflammatory bowel disease without obscuring the diagnostic capabilities of colonoscopy or biopsy analysis.

Rare adverse events in patients receiving PEG have been reported and include nausea with and without vomiting, abdominal pain, pulmonary aspiration, Mallory-Weiss tear, PEG-induced pancreatitis and colitis, lavage-induced pill malabsorption, cardiac dysrhythmia, and the syndrome of inappropriate antidiuretic hormone. An increase in plasma volume has been shown to occur in some individuals with concomitant disease states that predispose them to fluid retention. Adverse effects may occur less frequently in association with preparation regimens that use a reduced volume of PEG. Some drug interaction databases raise concerns when PEG solutions, especially HalfLytely®, are prescribed for patients taking angiotensin converting enzyme (ACE) inhibitors and/or potassium-sparing diuretics because of the small amount of potassium present in this preparation solution. Although this problem raises a theoretic concern for hyperkalemia in these patients, no clinical reports of adverse outcomes were available as of this writing.

The use of NaP is associated with physiologically significant, although rarely clinically meaningful, changes in volume status and electrolyte abnormalities. NaP preparations have been shown to alter both the macroscopic and microscopic features of intestinal mucosa, and induce aphthoid erosions similar to those seen in inflammatory bowel disease, which may obscure the diagnosis of inflammatory bowel disease. For this reason, many clinicians avoid using NaP preparations in patients undergoing diagnostic colonoscopy for suspected inflammatory bowel disease or microscopic colitis.

NaP is available as a bowel preparation for colonoscopy in both liquid and solid tablet form. The following adverse events are characteristic of both formulations. Serum electrolyte abnormalities and extracellular fluid volume is altered, initially by increasing fluid retention, and then causing significant losses of both fluid and electrolytes in the stool effluent. The significant volume contraction and resultant dehydration seen in some patients using NaP preparations may be lessened by encouraging patients to drink fluids liberally during the days leading up to their procedure, especially during their preparation. Although usually asymptomatic, hyperphosphatemia is seen in as many as 40 percent of healthy patients completing NaP preparations, and may be significant in patients with renal failure. As many as 20 percent of patients using NaP preparations develop hypokalemia; in addition, NaP has been shown to cause elevated blood urea nitrogen levels, decreased exercise capacity, increased plasma osmolality, hypocalcemia, and significant hyponatremia and seizures. These significant blood chemistry abnormalities are more profound in children; therefore, NaP should not be used in children with acute and chronic renal failure, congestive heart failure, ileus, and ascites. Rare adverse events, such as nephrocalcinosis with acute renal failure, also have been reported after NaP preparation for colonoscopy particularly in those patients with hypertension receiving ACE inhibitors or angiotensin receptor blockers (ARBs).

Contraindications

Contraindications

Sodium phosphate (NaP) is contraindicated in patients younger than five years of age and those with serum electrolyte imbalances, advanced hepatic dysfunction, acute and chronic renal failure, recent myocardial infarction, unstable angina, congestive heart failure, ileus, malabsorption, and ascites.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Wexner SD, Beck DE, Baron TH, Fanelli RD, Hyman N, Shen B, Wasco KE, American Society of Colon and Rectal Surgeons, American Society for Gastrointestinal Endoscopy, Society of American Gastrointestinal and Endoscopic Surgeons. A consensus document on bowel preparation before colonoscopy: prepared by a task force from American Society of Colon and Rectal Surgeons, American Society for Gastrointestinal Endoscopy, and Society of American Gastrointestinal and Endoscopic Surgeons. Gastrointest Endosc. 2006 Jun;63(7):894-909. [116 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2006 Jun (reaffirmed 2011)

Guideline Developer(s)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

American Society of Colon and Rectal Surgeons - Medical Specialty Society

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

Source(s) of Funding

American Society for Gastrointestinal Endoscopy

Guideline Committee

Task Force from The American Society of Colon and Rectal Surgeons (ASCRS), the American Society for Gastrointestinal Endoscopy (ASGE), and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

Composition of Group That Authored the Guideline

Task Force Members: Steven D. Wexner, MD (*Task Force Chair*); David E. Beck, MD (*ASCRS*); Todd H. Baron, MD (*ASGE*); Robert D. Fanelli, MD (*SAGES*); Neil Hyman, MD (*ASCRS*); Bo Shen, MD (*ASGE*); Kevin E. Wasco, MD (*SAGES*)

Financial Disclosures/Conflicts of Interest

Steven D. Wexner, MD, Scientific Advisory Panel to C.B. Fleet; David E. Beck, MD, Consultant, Braintree Salix; Todd H. Baron, MD, None, Robert D. Fanelli, MD, None; Neil Hyman, MD, None; Bo Shen, MD, Consultant to Salix, Visicol; Kevin E. Wasco, MD, None

Guideline Status

This is the current release of the guideline.

The guideline was reaffirmed for currency by the developer in 2011.

Guideline Availability

Electronic copies: Available from the American Society for Gastrointestinal Endoscopy Web site .

Print copies: Available from Steven D. Wexner, MD, Department of Colorectal Surgery, Cleveland Clinic Florida, 2950 Cleveland Clinic Blvd., Weston, FL 33331; Email: mcderme@ccf.org

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on October 5, 2006. The information was verified by the guideline developer on October 31, 2006. This summary was updated by ECRI Institute on January 7, 2009 following the U.S. Food and Drug Administration (FDA) advisory on oral sodium phosphate (OSP) products for bowel cleansing. This summary was updated by ECRI Institute on April 1, 2009 following the FDA advisory on Reglan (metoclopramide). The currency of the guideline was reaffirmed by the developer in 2011 and updated by ECRI Institute on November 3, 2011.

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